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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,089	05/19/2004	Marc Nazare	DEAV2003/0033 US NP	5674

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EXAMINER	
SHIAO, REI TSANG	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/849,089	NAZARE ET AL.	
	Examiner	Art Unit	
	Robert Shiao, Ph. D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *9 and 11-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/08/05, 10/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

6/15/07

DETAILED ACTION

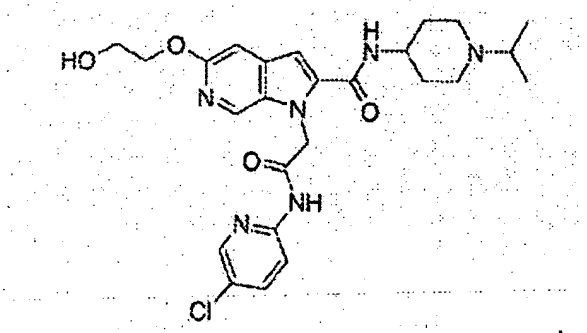
1. Claims 1-15 are pending in the application.

Information Disclosure Statement

2. Applicant's Information Disclosure Statements, filed on December 08, 2005, October 19, 2004 and June 25, 2004, have been considered. Please refer to Applicant's copies of the 1449's submitted herein.

Responses to Election/Restriction

3. Applicant's election with traverse of Group III claims 1-8 and 10, in part, in the reply filed on October 16, 2006, is acknowledged. Applicant's election of a species, i.e.,



. , is also acknowledged. The traversal is on the grounds that the Examiner has failed to provide sufficient reasons in support of a restriction between the inventions of Groups I-V, and M.P.E.P. 803, and 816 are cited. This is found not persuasive, and the reasons are given *infra*.

Claims 1-15 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Claims 1-8 and 10, in part, drawn to compounds/compositions of formula (I), wherein the variables Q, R^1, R^2, R^3, R^8, R^{11}, R^{12}, R^{13}, and G independently do not represent heteroaryl or heterocyclyl thereof; the variables Q, R^1, R^2, R^3, R^8, R^{11}, R^{12}, R^{13}, and G independently are not substituted with heteroaryl or heterocyclyl thereof; the variable D represents aryl or pyridyl thereof; the variable R^0 represents aryl, pyridyl, or isoxazolyl substituted with thienyl thereof; the heteroaryl or heterocyclyl of the variable V or M independently is selected from piperidine, pyridine, imidazole, isothiazole, oxazole, pyrrolidine, tetrazole, or thiazole thereof; the variables R^1 and R^3 together with the atom to which they are attached do not form a cyclic group thereof; the variables R^1-N-R^2-V together do not form a cyclic group thereof; the variables R^{11} and R^{12} together with the atom to which they are attached do not form a heterocyclic ring thereof.

The withdrawn compounds contain varying heterocycle or heteroaryl of the variable R^0, V or M of the formula (I) having pyrimidinyl, azepane, morpholine, or piperazine moiety, which differ from those of the elected invention having pyridyl moiety, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classifications of these functional groups in the U.S. classification system, i.e., class 544 subclass 242(+) (pyrimidinyl), class 544 subclass (336+) (piperazine), class 540 subclass 484(+) (azepane), class 544 subclass (106+) (morpholine), etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in common structure and have been restricted properly.

Groups I-III and Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product having a pyrrolo/pyridine moiety as claimed can be practiced with another materially different product, see WO 2002062423 or CAS:137:169502, or see US 6,436,965.

The group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Claims 1-8 and 10, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 1-8 and 10, in part, not embraced in above elected subject matter, and claims 9 and 11-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Labelle et al. US 6,436,965.

Applicants claim indole compounds of Formula (I), wherein the variable D represents aryl or pyridyl, as agents treating inflammatory response or conditions, see claim 1. Dependent claims 2-8 and 10 further limit a number of variables, i.e., R^0 represents aryl.

Labelle et al. disclose a number of indole compounds, see compounds No. 149-152, 156-158 and 160 in column 53. Labelle et al. compounds clearly anticipate the instant compounds of formula (I), wherein the variable D represents aryl, the variable Q represents –(C_1-C_6)-alkylene (i.e., methyl), the variable R^0 represents aryl substituted with halogen or -(C_1-C_4)alkyl (.e., benzyl-4Bu or benzyl-4-F), the variable R^3 represents -(C_0-C_4)-alkylene-O-R19 and R19 represent -(C_1-C_4)-alkylene substituted with R13, and

R13 represents -(C_3-C8)cycloalkyl (i.e., R^3 is O-CH_2-cyclopropyl), the variable R^1 represents hydrogen, the variable R^2 is a direct bond, the variable V represent aryl or heterocycle (i.e., phenyl or pyridyl) optionally substituted with R14 and R14 represents -(C_1-C_4)alkoxy (i.e., methoxy) or halogen (i.e., F), the variable G is a direct bond, the variable M is hydrogen. Dependent claims 2-8 and 10 also rejected along with claim 1 under 35 U.S.C. 102(b).

6. Claims 1-8 and 10 are rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by Nazar'e et al. US 6,906,084. Nazar'e et al. '084 is 102 (e) reference.

Applicants claim indole compounds of Formula (I), wherein the variable D represents aryl or pyridyl, as agents treating inflammatory response or conditions, see claim 1. Dependent claims 2-8 and 10 further limit a number of variables, i.e., R^0 represents aryl.

Nazar'e et al. disclose a number of indole compounds, see Examples 1-276, in column 41-190. Nazar'e et al. compounds clearly anticipate the instant compounds of formula (I), wherein the variable D represents aryl (i.e., phenyl), the variable Q represents –(C_1-C_6)-alkylene (i.e., methyl), the variable R^0 represents phenyl or isooxazole substituted with chloro-thiophene, the variable R^3 represents hydrogen, the variable R^1 represents hydrogen, the variable R^2 is a direct bond, the variable V represent aryl (i.e., phenyl) or heterocycle (i.e., piperidine) optionally substituted with R14 and R14 represents -(C_1-C_4)alkoxy (i.e., methoxy) or halogen (i.e., F), the variable G is a direct bond or –(CH2)m-NR^{10} and m is zero and R^{10} is hydrogen, the variable M

is aryl (i.e., phenyl) or heterocycle (i.e., pyridyl, piperidine or pyrrolidine) or $-(C_1-C_8)$-alkyl (i.e., ethyl). Dependent claims 2-8 and 10 also rejected along with claim 1 under 35 U.S.C. 102(a) or 102(e).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

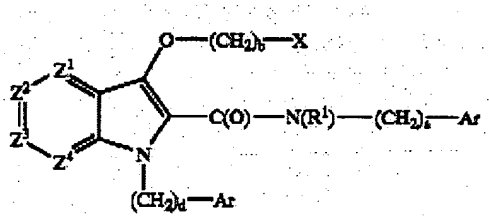
under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as being obvious over Labelle et al. US 6,436,965.

Applicants claim compounds/compositions of Formula (I) as agents treating inflammatory response or conditions, see claim 1. Dependent claims 2-8 and 10 further limit a number of variables, i.e., R^0 represents aryl.

Determination of the scope and content of the prior art (MPEP §2141.01)

Labelle et al. disclose compounds/compositions of formula (I), i.e.,



, wherein the variable Z^4 represents N, Z^1-Z^3 independently represents CR^2, or Z^1-Z^4 independently represents CR^2, the variable Ar independently represents phenyl, thienyl, thiazolyl, pyridyl, oxazolyl, tetrazolyl, pyrimidinyl, pyrazinyl or pyridazinyl, the variable X represents C_{3-7} cycloalkyl or Ar; and the variable R^1 and R^2 independently represent hydrogen or C_{1-4} alkyl, see columns 41-42. Labelle et al. compounds are used as agents for treating inflammatory response or conditions, see columns 57-58.

Determination of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and Labelle et al. is that the instant variable R^0 of instant claims represents aryl (i.e., phenyl), pyridyl or isooxazole, while Labelle et al. represents phenyl or pyridyl at the same position.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the instant claims 1-8 and 10 prima facie obvious **because** one would be motivated to employ the compounds/compositions of Labelle et al. to obtain the instant compounds/compositions of Formula (I), wherein the variables Q, R^1, R^2, R^3, R^8, R^{11}, R^{12}, R^{13}, and G independently do not represent heteroaryl or heterocyclyl thereof; the variables Q, R^1, R^2, R^3, R^8, R^{11}, R^{12}, R^{13}, and G independently are not substituted with heteroaryl or heterocyclyl thereof; the variable D represents aryl or pyridyl thereof; the variable R^0 represents aryl, pyridyl, or isoxazolyl substituted with thienyl thereof; the heteroaryl or heterocyclyl of the variable V or M independently is selected from piperidine, pyridine, imidazole, isothiazole, oxazole, pyrrolidine, tetrazole, or thiazole thereof; the variables R^1 and R^3 together with the atom to which they are attached do not form a cyclic group thereof; the variables R^1-N-R^2-V together do not form a cyclic group thereof; the variables R^{11} and R^{12} together with the atom to which they are attached do not form a heterocyclic ring thereof. Dependent claims 2-8 and 10 are also rejected along with claim 1 under 35 U.S.C. 103(a).

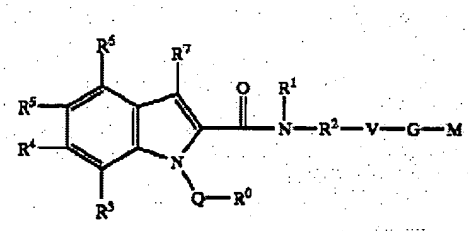
The motivation to obtain the claimed compounds derives from known Labelle et al. compounds/compositions would possess similar activities (i.e., treating inflammatory response or conditions) to that which is claimed in the reference.

9. Claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as being obvious over Nazar'e et al. US 6,906,084. Nazar'e et al. '084 is 102 (e) reference.

Applicants claim compounds/compositions of Formula (I) as agents treating inflammatory response or conditions, see claim 1. Dependent claims 2-8 and 10 further limit a number of variables, i.e., R^0 represents aryl.

Determination of the scope and content of the prior art (MPEP §2141.01)

Nazar'e et al. disclose compounds/compositions of formula (I), i.e.,



, wherein the variable Q is a direct bond, the variable R^0 represents aryl or heteroaryl, the variable R^1 represents hydrogen, the variable R^2 represents $-(C_1-C_4)$-alkylene, the variable V represents piperidine, the variable G represents a direct bond, the variable M represents hydrogen or $-(C_1-C_8)$-alkyl, see columns 193-194 and 209-210. Nazar'e et al. compounds are used for treating thrombus formation.

Determination of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and Nazar'e et al. is that the instant variable D of instant claims represents aryl (i.e., phenyl) or pyridyl, while Nazar'e et al. represents aryl (i.e., phenyl) at the same position.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the instant claims 1-8 and 10 prima facie obvious **because** one would be motivated to employ the compounds/compositions of Nazar'e et al. to obtain the instant compounds/compositions of Formula (I), wherein the variables Q, R^1, R^2, R^3, R^8, R^{11}, R^{12}, R^{13}, and G independently do not represent heteroaryl or heterocyclyl thereof; the variables Q, R^1, R^2, R^3, R^8, R^{11}, R^{12}, R^{13}, and G independently are not substituted with heteroaryl or heterocyclyl thereof; the variable D represents aryl or pyridyl thereof; the variable R^0 represents aryl, pyridyl, or isoxazolyl substituted with thienyl thereof; the heteroaryl or heterocyclyl of the variable V or M independently is selected from piperidine, pyridine, imidazole, isothiazole, oxazole, pyrrolidine, tetrazole, or thiazole thereof; the variables R^1 and R^3 together with the atom to which they are attached do not form a cyclic group thereof; the variables R^1-N-R^2-V together do not form a cyclic group thereof; the variables R^{11} and R^{12} together with the atom to which they are attached do not form a heterocyclic ring thereof. Dependent claims 2-8 and 10 are also rejected along with claim 1 under 35 U.S.C. 103(a).

The motivation to obtain the claimed compounds derives from known Nazar'e et al. compounds/compositions would possess similar activities (i.e., treating thrombus formation) to that which is claimed in the reference.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

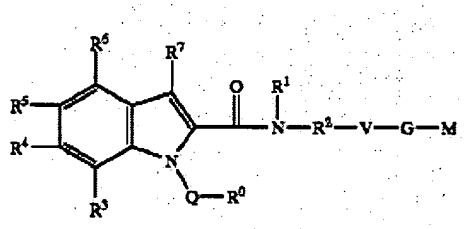
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-8 and 10 are rejected under the judicially created doctrine of

obviousness-type double patenting as being unpatentable over claims 1 and 6 of Nazar'e et al. US 6,906,084. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim compounds/compositions of Formula (I) as agents treating inflammatory response or conditions, see claim 1. Dependent claims 2-8 and 10 further limit a number of variables, i.e., R^0 represents aryl.

Nazar'e et al. disclose compounds/compositions of formula (I), i.e.,



, wherein the variable Q is a direct bond, the variable R^0 represents aryl or heteroaryl, the variable R^1 represents hydrogen, the variable R^2 represents $-(C_1-C_4)$-alkylene, the variable V represents piperidine, the variable G represents a direct bond, the variable M represents hydrogen or $-(C_1-C_8)$-alkyl, see columns 193-194 and 209-210. Nazar'e et al. compounds are used for treating thrombus formation.

The difference between the instant claims and Nazar'e et al. is that the instant variable D of instant claims represents aryl (i.e., phenyl) or pyridyl, while Nazar'e et al. represents aryl (i.e., phenyl) at the same position.

One having ordinary skill in the art would find the instant claims 1-8 and 10 prima facie obvious **because** one would be motivated to employ the compounds/compositions of Nazar'e et al. to obtain the instant compounds/compositions of Formula (I), wherein

the variables Q, R^1, R^2, R^3, R^8, R^{11}, R^{12}, R^{13}, and G independently do not represent heteroaryl or heterocyclyl thereof; the variables Q, R^1, R^2, R^3, R^8, R^{11}, R^{12}, R^{13}, and G independently are not substituted with heteroaryl or heterocyclyl thereof; the variable D represents aryl or pyridyl thereof; the variable R^0 represents aryl, pyridyl, or isoxazolyl substituted with thienyl thereof; the heteroaryl or heterocyclyl of the variable V or M independently is selected from piperidine, pyridine, imidazole, isothiazole, oxazole, pyrrolidine, tetrazole, or thiazole thereof; the variables R^1 and R^3 together with the atom to which they are attached do not form a cyclic group thereof; the variables R^1-N-R^2-V together do not form a cyclic group thereof; the variables R^{11} and R^{12} together with the atom to which they are attached do not form a heterocyclic ring thereof. Dependent claims 2-8 and 10 are also rejected along with claim 1 under the obviousness-type double patenting.

The motivation to obtain the claimed compounds derives from known Nazar'e et al.compounds/compositions would possess similar activities (i.e., treating thrombus formation) to that which is claimed in the reference.

Claim Objections

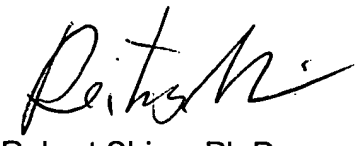
12. Claims 1-8 and 10 are objected to as containing non-elected subject matter, i.e., heteroaryl, monocycloheterocyclic or bicycloheterocyclic rings, heterocyclic ring, the variable R^{13} represents isooxazole, oxodiazole, triazole, or thiadiazole, etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on pages 2-3 *supra*.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

November 15, 2006